

The independent claims, claim 1, 26, and 51 appear in both groups, as do claims 2-3, 9-27, 28, 34-50, 52-54 and 60-75. Thus, the Examiner is seeking a two way restriction of claims 1-3, 9-28, 34-54 and 60-75. Applicants respectfully submit that this restriction is not proper.

Restriction practice is *not* applicable to a single claim, as doing so would violate the right of the Applicant to claim the invention with the limitations he regards as necessary. *See In re Weber*, 198 U.S.P.Q. 328, 332 (C.C.P.A. 1978) (“An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112”); *See also In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978). Copies of both cases are attached hereto as Exhibits A and B. These cases made it clear that 35 U.S.C. § 121 does not grant to the U.S.P.T.O. the authority to refuse to examine a single claimed invention. As recently as 2004, the U.S.P.T.O. has indicated that it considers *Weber* and *Haas* to be good law and that “it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention [as determined by the “single structural similarity” and “common utility” tests of *In re Harnisch*, 631 F.2d 716, 206 U.S.P.Q. 300 (C.C.P.A. 1980)].” TC1600 Restriction Training For Examiners, August 2004, at page 6. Available at: <http://www.uspto.gov/web/patents/tc1600restrictionmaterials.pdf>. The Examiner has not shown that the claims lack unity of invention under the tests elaborated by *Harnisch* and its related cases, and it is therefore improper to refuse to examine the invention as claimed.

Moreover, *Weber* and *Haas* made it clear that a refusal to examine a single claim based upon 35 U.S.C. § 121, *i.e.*, withholding a claim from consideration because it allegedly comprises independent or distinct inventions, is an appealable, as opposed to a petitionable matter.

If, however, the Examiner is asserting that the Application includes two or more otherwise properly divisible inventions that are linked by a claim which, if allowable, would prevent restriction, Applicants respectfully request that, in accordance with M.P.E.P. § 809.03:

- (a) the Examiner clarify this intent in the next communication from the Office and;
- (b) examine the elected group such that, upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability.

II. Groups I and II are Related Subject Matter

Even *if* the restriction of a single claim was allowed, or the Restriction was made in accordance with M.P.E.P. § 809.03, Groups I and II are related subject matter. For example, Groups I-II are both directed to a method of treating a disease by administering a first and second therapeutic agent and the composition comprising the first and second therapeutic agent. Furthermore, both of the groups are classified in Class 424, subclass 143.1. Accordingly, Applicants respectfully assert that Groups I and II are related subject matter.

III. Search and Examination of Both Groups Poses No Serious Burden

Even assuming, *arguendo*, that Groups I and II are not related subject matter, Applicants submit that to search and examine the subject matter of these Groups together would not be a serious burden on the Examiner. For example, a search for publications that disclose agonist antibodies for treating a disease would lead to publications that disclose antagonist antibodies for treating a disease. Accordingly, it would not be an undue burden for the Examiner to search Groups I-II together. The M.P.E.P. §803 (Eighth Edition, Rev. August, 2001) states:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, in view of the M.P.E.P. §803, Applicants respectfully request that all claims be searched and examined in the subject application. Therefore, reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

IV. Species Election

The Office Action also required an election of species. Applicants hereby provisionally elect:

- (A) for the method of treating: (6) cancer (claims 26-77 are readable thereon);
- (B) for the second therapeutic agent: (vii) a chemotherapeutic agent (claims 1-19, 22, 24-44, 47, 49-68, 71 and 73-77 are readable thereon); and
- (C) for the chemotherapeutic agent: (f) a platinum analog (claims 1-19, 24, 26-44, 49, 51-68, 73 and 75-77 are readable thereon).

These elections are made without prejudice to or disclaimer of the other claims or inventions disclosed.

These elections are made **with traverse**.

Applicants respectfully submit that to search and examine the subject matter of the method of treating various diseases would not be a serious burden on the Examiner. For example, a search for publications that disclose antibodies which bind Death Domain Containing Receptor-4 (DR4) for treating cancer would lead to publications that disclose antibodies which bind DR4 for treating other diseases. Accordingly, it would not be an undue burden for the Examiner to search all of the various diseases together.

Furthermore, Applicants respectfully submit that to search and examine the subject matter of second therapeutic agents would not be a serious burden on the Examiner. For example, a search for publications that disclose the use of a chemotherapeutic agent for treating disease would lead to publications that disclose the use of other therapeutic agents for treating disease. Accordingly, it would not be an undue burden for the Examiner to search all of the second therapeutic agents together.

Furthermore, Applicants respectfully submit that to search and examine the subject matter of various chemotherapeutic agents would not be a serious burden on the Examiner. For example, a search for publications that disclose the use of a platinum analog for treating disease would lead to publications that disclose the use of other chemotherapeutic agents for treating disease. Accordingly, it would not be an undue burden for the Examiner to search all of the chemotherapeutic agents together.

Finally, in accordance with 37 C.F.R. § 1.141(a), Applicants also reserve the right to claim additional species, and/or to have additional species searched and/or examined, in the event that a generic claim is found to be allowable.

With regard to the Examiner's statement on page 4 of the Office Action, the Examiner lists claims 1 and 3-19 as the only generic claims with respect to the second therapeutic agent. Applicants respectfully assert that claims 2, 26-44, 51-68, and 75-77 are also generic with respect to the second therapeutic agent. For example, claim 2 and claim 3 are both directed to the first therapeutic agent that comprises an antibody that binds to the extracellular domain of DR4, but are generic with respect to the second therapeutic agent. In addition, independent claims 26 and 51 contain identical language as claim 1 with respect to the second therapeutic agent. Applicants respectfully request that the Examiner clarify in the next communication from the Office.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Shannon A. Carroll, Ph.D.
Attorney for Applicant
Registration No. 58,240

Date: July 10, 2006

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
546187_1.DOC